ASEAN Guidelines on GMP for Traditional Medicines

Chapter 8 – Contract Manufacture and Contract Analysis

Prepared by:

AATMI/Philippines

Approved by:

ASEAN TMHS GMP Task Force

Endorsed by:

ASEAN TMHS Product Working Group

Outline

- Principle
- Contract Manufacture
- Contract Analysis
- The Contract Giver
- The Contract Acceptor
- The Contract

Principle

- Contract manufacture and analysis must be correctly defined, agreed and controlled in order to avoid misunderstandings which could result in a product or work of unsatisfactory quality.

- There must be a written contract between the Contract Giver and the Contract Acceptor which clearly establishes the duties and responsibilities of each party.

- The contract must clearly state the way in which the authorized person releasing each batch of product for sale exercises his full responsibility.

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Manufacture is defined as:

- (a) the making or assembling of the finished product, (TM or HS in this presentation)
- (b) the enclosing or packing of the finished product in any container in a form suitable for administration or application, and the labelling of the container, and
- (c) the carrying out of any process in the course of any of the foregoing activities."

Ref: ASEAN Guidelines on GMP for TM & HS (Guideline)

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Analysis is defined as:

Assessing the quality of medicinal plants, herbal materials, and finished herbal products before they reach the market according to pharmacopeia or internationally accepted references for test methods.

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Contract Manufacture

Contract manufacture shall have a written contract agreement between the contract giver and the Contract Acceptor, which clearly establishes the duties and responsibilities of each party. All arrangements for contract manufacture, including any proposed changes in technical or other arrangements, shall be in accordance with the NRA requirements for the product concerned.

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Contract Analysis

- Contract analysis must have a written contract agreement between the contract giver and the Contract Acceptor which clearly establishes the duties and responsibilities of each party.

- All arrangements for contract analysis, including any proposed changes in technical or other arrangements, shall be in accordance with NRA's requirements for the product concerned.

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The Contract Giver shall :

- be responsible for assessing the competency of the Contract Acceptor in successfully carrying out the work/test required and for ensuring by means of the contract that the principles of GMP described in these guidelines are followed.

- provide the Contract Acceptor with all the information (e.g. technical data, standard and requirements of the product or the analytical methods of the product TM or HS) necessary to carry out the contracted operations correctly in accordance with the NRA requirements.

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The Contract Giver shall :

- ensure that the Contract Acceptor is fully aware of any problems associated with the product or the work which might pose a hazard to his premises, equipment, personnel, other materials or other products.
- ensure that all products and materials delivered by the Contract Acceptor comply with their specifications.

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Contract Acceptor Responsibilities:

- Must have **adequate** premises, equipment, knowledge, experience and **competent** personnel.
- Contract manufacture shall be undertaken only by a manufacturer who is the holder of a manufacturing authorization issued by the NRA.
- Should ensure that all **products/materials** delivered **are suitable** for their intended purposes

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Contract Acceptor Responsibilities:

- Should not pass on to a 3rd party any of the work entrusted to him under contract without the contract giver's prior evaluation/approval of the arrangement.
- Should refrain from any activity which may adversely affect the quality of the product manufactured and/or analysed for the contract giver.

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The Contract

Drawn up between the Contract Giver and Contract Acceptor

- Should **specify** the respective **responsibilities** relating to the manufacture & control of the product. **Both Contract Giver & Contract Acceptor are responsible for the quality of the product.**
- Should **specify** the way in which the **authorized person releasing** the batch for sale ensures that each batch has been manufactured & checked for the compliance with requirements of Marketing Authorization.

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The Contract

- Should **describe clearly who is responsible** for **purchasing** materials, testing & releasing them, undertaking production & quality controls including the in-process control and who has responsibility for samples & analysis.
- Should **indicate** list of **products** for contract manufacturing.

In the case of **contract analysis**, the contract should state whether or not the contract acceptor **should take samples** at the premises of the manufacturer, **indicate** a **sampling plan**, **quantity** of sample and sampling **container**.

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The Contract

- Manufacturing, analytical, distribution records & reference samples should be kept by or be available to Contract Giver.
- Any **records** relevant to assessing the quality of a product or a suspected defect must **be accessible** & specified in the defect/recall procedures of the Contract Giver.
- Should **permit** the Contract Giver to **visit the facilities** of the Contract Acceptor.
- In case of contract analysis, the Contract Acceptor should understand that he is subject to inspection by the competent authorities

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(To provide samples on contract)

Reference